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krouwel, Matthew; Jolly, Kate; Greenfield, Sheila

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How do people with refractory irritable bowel syndrome perceive Hypnotherapy: qualitative study protocol

Matthew Krouwel BA*, Professor Kate Jolly PhD, Professor Sheila Greenfield PhD.

Institute of Applied Health Research, University of Birmingham, Edgbaston, Birmingham, B15
2TT

***Corresponding author at 80, Hawkesley Mill Lane, Northfield, Birmingham B31 2RI**

Mattkrouwel@gmail.com

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Abstract

Introduction – irritable bowel syndrome (IBS) is a common condition which has significant impact on quality of life and has proven resistant to treatment. Hypnotherapy was recommended in National Institute of Health and Care Excellence (NICE) guidelines for the treatment of the refractory form of IBS in 2008. There is a dearth of research into the acceptability of hypnotherapy to people with IBS for their condition.

Methods – A qualitative study will be undertaken consisting of semi-structured one-to-one interviews with UK adults who have had a diagnosis of IBS for more than 12 months and continue to experience symptoms despite pharmacological intervention. Recruitment will be via large scale employers and through online IBS support and self-help groups, with snowballing from interviewees. Fifteen to twenty-five interviews will be conducted, both in person and via electronic real-time communications platforms (video calling) such as Skype. Interviews will be analysed using the framework method and will be coded twice. The first time will be inductive open coding for naturally occurring themes and the second will be theory driven deductive coding from a set of codes relating to Max Weber's antagonistic sources of power, 'Bureaucracy' and 'Charisma', which will help to identify people's conceptualisation of hypnosis.

Results - Findings will be disseminated at conferences and through peer-reviewed journals.

Discussion – The study will aid in identifying possible barriers to the use of hypnotherapy in the treatment of IBS, particularly any which relate to the perceptions of hypnosis and hypnotherapy.

1.Introduction

Irritable Bowel Syndrome (IBS) is a disorder of the gut-brain interaction [1] characterised by abdominal discomfort and a high level of variability in bowel movement frequency and form [2]. No universal prevalence figure can be agreed upon due to historical differences in diagnostic criteria and methodological issues with research [3, 4]. However, it appears to be a common condition, with studies in individual countries finding prevalence rates ranging from 1.1% [5] to 30.9% [6] and one study suggesting a potential global prevalence of 11.2% [7]. Although not life threatening, IBS is associated with substantial negative impacts on health related quality of life (HRQOL) [8] and a doubling or greater risk of suicidal behaviours when compared to healthy individuals [9]. Further, IBS is considered a difficult to treat condition [3, 10, 11] for which pharmacological approaches have limited success [10]. As a result, people with IBS often find it an expensive condition to live with, frequently expending on over the counter (OTC) remedies and complementary and alternative therapies (CAM) [12]. IBS is also expensive for the healthcare sector with one study from 2014 estimating that despite an apparently low cost to treat, IBS has a high prevalence and many costs due to related morbidity, meaning that the UK's National Health Service (NHS) may be spending £250 million a year or more because of IBS [13]. A US study identified an indirect impact cost of IBS, from such factors as lost days of work, of \$791 to \$7547 per person with IBS per annum [14]. The burden of IBS on people with the condition, the healthcare sector and society as a whole is therefore substantial.

Due to issues such as low responsiveness to pharmacological treatment, clinicians and academics have explored novel potential treatment strategies [15-17]. These treatments include psychological approaches, such as mindfulness [18] and CAM therapies such as probiotics, acupuncture, reflexology and Chinese herbs [19]. Amongst these novel treatments a number have been included in the UK's National Institute of Health and Care Excellence (NICE) guidelines, these include cognitive behavioural therapy (CBT), exercise, the FODMAP diet and hypnotherapy [20]. Hypnotherapy was first recommended in the NICE guidelines in 2008, as a psychological treatment approach to be considered for the treatment of refractory IBS [20] a sub category of IBS patients for whom it has demonstrable effectiveness [21, 22]. Refractory IBS is defined as IBS which has not responded to pharmacological intervention and where a continuous profile of symptoms is present twelve months or more after diagnosis [20].

Hypnotherapy is a broad therapeutic approach which may treat a condition through the use of the state of hypnosis combined with suggestion, in the form of words and metaphor [23], or by the application of adapted techniques from the various schools of psychotherapy, such as CBT [24] or psycho-dynamics [25]. There are two dominant approaches to the hypnotherapeutic treatment of IBS, these are the North Carolina Protocol [26] and the Manchester Model [27], although other variations do exist [28], collectively these are known as Gut Directed Hypnotherapy (GDH). GDH is a multiple session treatment protocol, typically taking between seven [26] and twelve sessions [29] which encourages digestive strength, regularity and calmness through imagery and suggestion [30]. Exactly how hypnotherapy effects change in IBS is unclear [31]: there is evidence which suggests that it may affect digestive motility [32], that it may be due to

cognitive alteration [33] or changes in perception of bowel distension [34]. A recent study suggested that hypnotherapy may be broadly moderating the posterior insula region of the brain, an area associated with the processing of signals from the body [35]. This could result in a decrease in the sense of urgency about bowel function as well as decreasing the discomfort and pain [36].

It is unclear how popular hypnotherapy is with people with IBS as very little research has been conducted. Figures regarding the current availability and use of hypnotherapy for IBS in the UK do not seem to exist, and their value would be debatable as it appears that provision of hypnotherapy services for IBS within the UK healthcare system is geographically variable, with a few areas benefiting from centres which treat dozens or even hundreds of patients a year, such as the Hypnosis Unit, Wythenshawe Hospital, Manchester [29, 37] or Sandwell's Nurse led Hypnotherapy service [38] but many areas appear to have no NHS services. Private hypnotherapy services appear to be widely available in the UK but there is little evidence that they are being accessed by people with IBS. One UK based study from 2008 found that 63.7% of 256 people with IBS would, in principle, consider hypnotherapy an acceptable treatment [39]. This mirrors the existing quantitative research into the public perception of hypnotherapy which suggests the majority of the public are positive towards it, although this is conditional upon the perceived qualifications of the therapist and their endorsement by the medical establishment, such as through a referral from their doctor [40]. However, this is theoretical data, how many actually use it is unclear. A US study of 419 people with IBS found that just 1.4% had actually used hypnotherapy, whereas more than double the number had been for acupuncture (3.3%), more than five times the number had seen a

psychotherapist (8.1%) and nine times the number had been for massage therapy(12.6%) [12]. This suggests that there may be some inhibition, specific to hypnotherapy, between what is theoretically acceptable and actual behaviour. What may cause this is highly speculative, one theory is that hypnosis is surrounded by myths [41] often perpetuated by images in popular media which may be intimidating, controlling or sexualised [42], in particular the hypnotist has a long history of being portrayed as possessing abilities which appear supernatural [43]. As media stereotypes can influence an individual's perceptions [44, 45] it is possible that these supernatural qualities are predominant in the public mind and may even be a barrier to hypnotherapy's use. There is evidence that hypnotherapists are conscious of the influence upon the perception of hypnotherapy which at the least stage hypnosis exerts, for example the British Society of Clinical Hypnosis (BSCH) explicitly prohibits members from using hypnosis for entertainment purposes.[46] Conversely it is possible that any perception of hypnotherapy which associates it with glamour or power may enhance its status. To address this issue Max Weber's antagonistic concepts of charismatic and bureaucratic power [47] may prove useful. Weber provides a model of power which conceives of one extreme as magical and personality driven (charisma) and the other as professional and systemised (bureaucracy), which would appear to encapsulate this tension effectively. However, lack of availability or the costs of treatment may also be at the root of the inhibition, currently we do not know because there is an almost complete absence of research into the views of people with IBS towards hypnotherapy which might help to explain and thus manage this gap. People with IBS's perception of hypnotherapy is likely to be both complex and nuanced, which makes qualitative

methods appropriate because of their ability to identify currently unknown factors whilst maintaining the human perspective [48] and they tend to produce more natural answers which are less influenced by factors such as saying the right thing [49] thus allowing the researcher to get closer to the subjective truth.

There already exists a wide body of qualitative research regarding the general subject of IBS, which covers the patient's experience of living with IBS [50-61], their encounters and engagement with the health care system [57, 62-64], their perceptions of specific treatment modalities [65-68] and general practitioners' opinions of the condition [60, 61, 69-71]. This body of research includes samples of both genders [50-56] from a variety of countries, including: Iran [50], China [58], Finland [66], Australia [60], Romania [64], Sweden and Norway [54, 56, 59, 62, 63], Canada [55, 72, 73], the United States of America [51, 52] and the UK [39, 53, 57, 61, 65, 67, 68, 70, 71]. However, some of the literature is not solely focused on IBS, and presents data which includes conditions such as chronic fatigue syndrome [69] and inflammatory bowel disease (IBD) without differentiating the findings by condition [72, 73], which limits its value. Some of the literature has a strong theoretical foundation, possibly inspired by the higher number of women with IBS than men [59], gendered perspectives appear to be predominant, such as feminist theory [63] and constructivist gender theory [59]. A major theme which arises from this work is dissatisfaction and disaffection with medical practitioners [51, 53, 54, 57-59, 61-63] although a lesser theme is present of encounters with medical practitioners in which the person with IBS felt validated [52, 61-63]. The next most substantial topic is that of personal efficacy and resilience in the face of IBS. Within this topic can be seen elements of people with IBS seeing themselves as a hero in battle

with IBS [63, 69], other psychological coping strategies [50, 53, 56, 62, 68], self-instigated behaviour changes [50, 52-54, 56, 57, 62], particularly around food and diet [52, 56-58], as well as stress management [54, 57, 58, 63, 66] and the use of CAM treatments [39, 58]. Only two pieces of work directly address the topic of hypnotherapy for IBS, one of which conducts interviews following hypnotherapy [74] and with the other hypnotherapy is only one of a number of topics addressed. This second article does however hint at a possible reason why some people with IBS may reject this potentially effective treatment, this being that hypnotherapy is perceived as more appropriate for mental rather than physical problems [39]. However, this is only one statement, much of the other data is vague, with phrases such as “I just don’t fancy it” being recorded, and ultimately the study only recorded five sentences, totalling less than forty words, related to hypnotherapy for IBS from a total study population of 256 [39]. With such a limited understanding of the perceptions of hypnotherapy by people with IBS any healthcare provider considering the provision of such a service is lacking even a rudimentary understanding of the potential patient’s perspective and knowledge of possible barriers to use of the service and what educational materials to give patients, both for their general understanding and so that they can give genuinely informed consent. This qualitative study will therefore undertake to identify the attitudes and opinions of people with IBS towards hypnotherapy as a treatment for their condition which will provide valuable information for services and practitioners who are considering the provision of hypnotherapy and thus aid in the development of a more effective service. This study will use one-to-one, face-to-face, semi-structured interviews[75] to explore the views of

people with refractory IBS about hypnotherapy and potential factors which may inhibit its usage.

2. Methods

2.1 Theory

2.1.1 Paradigm Position

The authors have adopted an interpretivist stance, this is one which views the world as the construct of individual's interactions.[76] In practice this means that the researchers accept their own influence upon the material generated and that the voice of those speaking is a true and authentic representation of their reality, even if that reality cannot be empirically validated. This has been adopted to reflect Max Weber's stance.[77]

2.1.2 Theoretical framework

Max Weber's conceptualisation of the source of authority, leadership and power [47] provides the theoretical basis for the research. Weber conceived two antagonistic concepts of authority in the world, charisma & bureaucracy [47]. A person is imbued with charismatic authority when they are perceived to be exceptional in some way, that they possess some characteristic which sets them above normal people, be this heroism, an exemplary character, or supernatural or superhuman abilities [47]. Weber's other conceptualisation of power, bureaucracy, is characterised by structure [47]. Within professions this is identified by the presence of vocational qualifications based on rational thinking within a definable system of knowledge [47]. In addition, other elements which may be present within a fully realised profession are that it is the sole occupation

of the practitioner and that it is acknowledged as a specialist role [78]. In this model hypnotherapy in the UK could be argued to be an emerging profession which is building the markers of bureaucratic authority, increasingly having externally validated qualifications and self-regulatory bodies [79]. However, as none of this is either formally or informally universal and a practitioner may have anything from a post graduate qualification to no qualification, it cannot yet be said to be an established profession [79]. In addition, it can be seen from previous quantitative research into public perceptions of hypnotherapy that most people are more open to hypnotherapy if it has an association with the medical or psychological establishment [40] which fits with Weber's concept of bureaucratic authority. Weber's theory has been used to explain and examine diverse environments [80-82] but to date we have been unable to identify its application within a health care setting. The research will attempt to establish whether the hypnotherapist is perceived as a figure of magic (charismatic), or a professional whose abilities are 'normal', learnable, regulated and scientific (bureaucratic).

2.1.3 Reflexivity and Trustworthiness

The three researchers all bring different perspectives, within the interpretivist paradigm this means that a reality will be constructed by the three researchers interacting with the participants. MK is a practicing hypnotherapist, a career which is likely to affect his perceptions and that of participants, to this end it has been decided to keep his profession undisclosed to participants unless they directly ask. KJ is a clinical academic, and SG is a medical sociologist, it is believed that the interaction of these three

professional backgrounds will serve to prevent a single perspective dominating the analysis.

2.2 Recruitment

Recruitment will be aimed directly at people with IBS, rather than through an NHS organisation, as the aim is to recruit people who are not currently engaged in seeking treatment as well as those who are. A convenience sample [83] of people with refractory IBS will be recruited using three main strategies, which in order of preference are:

1. Contacting on-line self-help and support groups.
2. Contacting local large employers
3. Paid on-line advertising

In addition, snowball sampling [84] will be used to maximise recruitment from these sources.

2.3 Sample

As a gender disparity is apparent in IBS, with an approximate ratio of two women having IBS to every man [85], an approximation of this division is aspired to. To this end gender focused versions of the recruitment strategies will be employed should natural recruitment not be sufficient. Although other demographic trends may be present in the IBS population none appear to be as pronounced as the gender division [86] and as such have not been prioritised. Recruitment will be ongoing through these strategies until an adequate sample size is achieved [87], When informed by data saturation this would be anticipated to be between 15-25 interviews [88, 89].

2.4 Interviews

2.4.1 Interview methods

Interviews will be individual, semi-structured and face-to-face. The semi-structured interview is considered to achieve an effective balance between providing topic orientation whilst allowing space for the interviewee to talk broadly [90]. The interview will either be in-person or conducted via a real-time electronic visual communications platform (video call) such as Skype [91]. Interviews via video calling have a number of theoretical advantages including financial savings [92], particularly in travel and related environmental benefits [93]. However, the primary advantage for this study was to capitalise on potential recruitment blooms, in which large numbers of potential candidates all volunteer simultaneously but are at high risk of loss of interest, a phenomenon which internet-based recruitment, with its ability to reach large numbers of people over a wide area, may generate. The choice to conduct interviews in-person or at a distance will be mutually agreed. When interviews are conducted in-person the choice of venue e.g. their home, café or local library, will be made by the interviewee. Both the decision to conduct distance interviews and to allow the interviewee to choose the location of the interview are in part motivated by the knowledge that many people with IBS become uncomfortable when they are unfamiliar with the location of lavatories in the local area [72]. When visiting people's homes or any other locations where the interviewer is likely to be vulnerable, appropriate measures to ameliorate risk will be taken [94].

2.4.2 Topic guide

A topic guide has been devised consisting of eleven primary questions, around the participant's experience of IBS, treatments for it, their perceptions of hypnosis and hypnotherapy, with both covert and overt questions that aim to capture data relating the Weberian conceptualisation of authority and bureaucracy.[47]

2.5 Participants

2.5.1 Inclusion criteria

- a. Potential participants have stated that they have a medical diagnosis of IBS.
- b. At least 18 years of age.
- c. Fulfil, by self-report, the NICE criteria for referral for psychological intervention.

This is 'people with IBS who do not respond to pharmacological treatments after 12 months and who develop a continuing symptom profile'[20]. This will be assessed at first contact with the question "Would you say that you have continued to experience symptoms for 12 months or more following pharmacological treatment?"

2.5.2 Exclusion criteria

- 1) Previous experience of hypnotherapy for IBS. These people are excluded on the grounds that their opinions and attitudes are retrospective rather than prospective.
- 2) Health care professional and allied professions with a specialism in gastrointestinal problems as they are likely to have prior exposure to information and medically orientated opinions and attitudes regarding hypnotherapy for IBS.

2.6 Consent

The interviewer will seek informed consent from potential participants for the interview, its recording and transcription and subsequent use within academic publications.

Recording and transcription are preferable to notes alone as they are demonstrably more accurate [95]. Issues of consent will be outlined in all written materials and for in-person interviews final consent will be obtained at the start of the face to face meeting prior to any formal topic related discussion and explained verbally before a signed consent form is completed by both interviewer and interviewee. For distance interviews consent will be first explained and sought off-record and then repeated in the recording once digital recording has been permitted by the interviewee. A consent form with return envelope will be posted to the distance interviewee. At any point up to a month after the interview the consent may be withdrawn without issue, as after the month the data will be integrated into the larger data set and not possible to disentangle.

2.7 Data analysis

Data analysis will be conducted at the first opportunity following each interview by MK, this will allow for a reflection upon the findings and a pause should it be deemed appropriate to make changes. Data will be analysed in two separate ways. The first of these will use thematic analysis [96], the researchers will conduct a process of 'open coding' [97], which consists of searching through the transcripts for all statements relating to IBS, hypnotherapy or any other topic which may be present and give these a code, for example 'IBS symptoms' or 'CAM treatment'. Once all the material has been coded the codes will be examined to amalgamate similar codes and exclude irrelevant

data, sometimes referred to as 'dross codes' [97]. This will produce a smaller number of codes and the material can then be coded again under this set of reduced codes. A matrix will be created which will include the codes on one axis and the data source (individual transcripts). This will allow the researchers to examine the data both by code across data sources and to contextualise each code within the wider context of the original transcript [98]. These tables will be examined and it is anticipated that between 5-10 themes will be identified which will be explored and written up [98]. All authors will read a selection of the transcripts to determine emerging themes and these will be discussed, and a selection agreed upon. This inductive coding will allow for a broad and relatively unbiased understanding of the data and provide evidence of data saturation [89].

The second analysis will again use the framework method [98], but this time it will be a deductive approach [99], based upon Weber's conceptualisation of sources of power. Prior to this analysis, codes relating to the theoretical basis will be determined from examination of both Weber's theory and of previous authors' writings about that work. These will be agreed by the authors in the same process as given above for open coding. Likely codes may include such topics as authority, science, magic, legitimacy, and professionalism. The transcripts will then be coded in line with this framework of codes, the codes will then be entered in to a matrix in the same way as for the open coded data detailed above.

NVivo software will be used for data management. Participants' demographic data will be entered into an excel spreadsheet and imported into NVivo with the appropriate transcripts and audio files linked.

2.8 Data protection and data management

The lead author (MK) will conduct all recruitment, interviews, data entry and transcription. Data collected in the field will remain in the possession of the interviewer at all times until it can be transferred into a lockable filing cabinet. During transcription anonymization will occur by the removal of names and each interviewee will be identified with a specific designation which will be used on paper file records and for electronic file names or transcripts and audio files. Separate and stand-alone documents will be used to identify participants with their file names which will be retained in a lockable metal filing cabinet. Only the lead researcher will have access to the original data. Upon direct and written request, in line with the Data Protection Act [100], interviewees will be able to access their own data records. At the end of the study all electronic data will be transferred to password protected secure servers at the University of Birmingham.

2.9 Ethics and dissemination

The study received ethical approval under the University of Birmingham's ethics procedures (reference ENR_15-1473). The study has no serious anticipated ethical issues; however, it is considered that the interview may touch upon personal issues and as such, efforts will be made to convey the importance placed upon anonymity and confidentiality. In addition, the research will prioritise the safety, well-being and confidentiality of the participants by anticipating and avoiding potential harms, avoiding unnecessary intrusion and respecting participants' right to withdraw at any time up to a month after the interview without the need to give a reason.

3. Results

Once the findings of this study are established a suitable peer reviewed journal/s will be sought for publication. The findings will be shared at an appropriate academic conference and a summary of the findings will be distributed to participants.

4. Discussion

This study will enable further understanding of the perceptions of people with refractory IBS towards hypnotherapy as a treatment for their condition, a topic which is currently almost entirely absent of research. To the best of our knowledge never before have the Weberian concepts of charisma and bureaucracy been used to understand the perception of an emerging medical approach and as such this will help to advance application of these theoretical concepts within a new setting to inform the wider canon of Weberian informed research.

4.1. Conclusion

The understandings gleaned will aid in the identification of possible barriers to the use of hypnotherapy by people with refractory IBS, in particular fears engendered by the perception of the hypnotherapist's source of authority, and as such will inform those considering the delivery of such a service, in particular with the design of patient educational materials.

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